K131694

510(k) Summary for the NMI Port II

Date prepared: 07-June-2013

A. Sponsor

Navilyst Medical, Inc
26 Forest Street
Marlborough, MA 01752

B. Contact

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508-658-7984

OR

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Vice President, Global Regulatory Affairs
508-494-1129

AUG 0 8 2013

C. Device Name

Trade Name:	NMI Port II
Common/Usual name:	Implanted Port Catheter, Subcutaneous,
Classification Name:	Implanted, Intravascular Infusion Port and Catheter
Classification Panel:	21CFR§880.5965, Class II General Hospital

D. Predicate Device(s)

Trade Name:	NMI Port
Common/Usual name:	Implanted Port Catheter, Subcutaneous,
Classification Name:	Implanted, Intravascular Infusion Port and Catheter
Classification Panel:	21CFR§880.5965, Class II General Hospital
Premarket Notification:	K122767

Trade Name:	NMI PICC III
Common/Usual name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Short and Long-Term Intravascular Catheter
Classification Panel:	21CFR§880.5970, Class II General Hospital
Premarket Notification:	K121089

E. Device Description

The NMI Port II with and without PASV Valve Technology is a subcutaneous implantable venous access device with one reservoir and is designed for optional power injection of contrast media, CECT. The ports are designed to be accessed using a non-coring Huber needle introduced through the skin into the self-sealing silicone septum covering the reservoir.

NMI Port II is available in plastic or titanium single lumen and valved or non-valved configurations. The ports are available with either silicone filled or non-filled suture fixation holes. Ports with non-filled suture fixation holes are generally utilized based on clinical need to anchor the port to the subcutaneous tissue; whereas ports with filled suture holes, designed to prevent tissue in-growth to the suture holes, are generally utilized when not anchoring the port to the subcutaneous tissue. If needed, filled suture holes are accessed through the silicone. All port configurations have a radiopaque identifier (CT mark) to identify the port as power injectable. The radiopaque catheter has graduated marks at 1 centimeter intervals and can be cut to the desired length by the clinician. Ports are provided with a variety of procedural accessories.

The catheter shaft incorporates Endexo polymer for improved resistance to thrombus accumulation and/or formation on the catheter.

F. Indication for Use

The NMI Port II with and without PASV Valve Technology is indicated for patients who require long-term access to the central venous system for administration of fluids including but not limited to hydration fluids, chemotherapy, analgesics, nutritional therapy and blood products. The device is also indicated for blood specimen withdrawal.

When used with a power injectable needle, the NMI Port II is indicated for power injection of contrast media. The maximum recommended infusion rate is 5 ml/sec with a 19G or 20G non-coring power injectable needle or 2 ml/sec with a 22G non-coring power injectable needle.

G. Summary of Similarities and Differences in Technological Characteristics and Performance

The proposed device has similar materials, design and components and technological characteristics as predicate devices. Both the NMI Port II and predicate ports are, in brief, intended for patients who require long-term access to the central venous system for administration of fluids including but not limited to hydration fluids, chemotherapy, analgesics, nutritional therapy and blood products; available in single lumen configurations; plastic or titanium port body available with either a 6F or 8F outside diameter catheter; rated for maximum power injector settings up to 300 psi with maximum power injection flow rate up to 5 ml/second based on model; and available kitted with a variety of procedural accessories.

H. Performance Data

The performance evaluation of the NMI Port II included testing conducting in accordance with the following FDA guidance documents and international standards:

- FDA's "Guidance on 510(k) Submissions for Implanted Infusion Ports dated October 1990.
- EN ISO 10555-1:2009, Sterile, Single Use Intravascular Catheters – Part 1: General Requirements
- EN ISO 10555-3:1997 COR 2002, Sterile, Single Use Intravascular Catheters – Part 3: Central Venous Catheters
- Biocompatibility per ISO 10993-1

The proposed NMI Port II successfully passed relevant testing per the above Guidance, standards, and pre-established acceptance criteria, including:

- Internal Product Specification Requirements
- Power Injection
- Valve Integrity
- Catheter Compatibility with Procedural Aid Devices
- Port Septum Testing
- Chemical / Vesicant Compatibility
- Thromboresistance

I. Conclusion

Based on successful results of testing and on responses to questions posed in FDA's 510(k) Decision Making Tree, the proposed device is determined to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 08, 2013

Navilyst Medical, Incorporated
C/O Mr. Brandon M. Brackett
Specialist, Global Regulatory Affairs
26 Forest Street
Marlborough, MA 01752

Re: K131694
Trade/Device Name: NMI Port II
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: June 7, 2013
Received: June 12, 2013

Dear Mr. Brackett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known): K131694

Device Name: NMI Port II

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Prescription Use (21 CFR 801 Subpart D)	☒	And/Or	AND/OR Over-The-Counter Use: (21 CFR 801 Subpart C)	☐

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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